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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, AKTIEBOLAGET
HÄSSLE, ASTRAZENECA LP, and
ZENECA INC.,

Plaintiffs,

v.

PERRIGO COMPANY PLC, PERRIGO
COMPANY, L. PERRIGO COMPANY, and
PADDOCK LABORATORIES, LLC,

Defendants.

Civil Action No.: 3:15-cv-01057-MLC-TJB

**PLAINTIFF'S ANSWER TO
PERRIGO COMPANY PLC, PERRIGO
COMPANY, AND L. PERRIGO
COMPANY'S COUNTERCLAIMS**

Plaintiffs / Counterclaim-Defendants AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, and Zeneca Inc. (collectively, “Plaintiffs”), by their attorneys, file this Answer to the Counterclaims of Defendant / Counterclaim-Plaintiffs Perrigo Company plc, Perrigo Company, and L. Perrigo Company (“Perrigo”) as follows:

ANSWER TO DEFENDANT’S COUNTERCLAIMS

PARTIES

1. On information and belief, Plaintiffs admit the allegations of paragraph 1.
2. On information and belief, Plaintiffs admit the allegations of paragraph 2.
3. On information and belief, Plaintiffs admit the allegations of paragraph 3.
4. Plaintiffs admit the allegations of paragraph 4.
5. Plaintiffs admit the allegations of paragraph 5.
6. Plaintiffs admit the allegations of paragraph 6.
7. Plaintiffs admit the allegations of paragraph 7.

Jurisdiction and Venue

8. The allegations of paragraph 8 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that Perrigo purports to state a cause of action under 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (“MMA”) (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)), but deny that there is any factual or legal basis for the declaratory judgment action or that Perrigo is entitled to the relief it seeks. Plaintiffs deny the remaining allegations of paragraph 8.

9. The allegations of paragraph 9 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that this Court has subject

matter jurisdiction over Plaintiffs, for this action only. Plaintiffs deny the remaining allegations of paragraph 9.

10. The allegations of paragraph 10 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that this Court has personal jurisdiction over Plaintiffs, for this action only. Plaintiffs deny the remaining allegations of paragraph 10.

11. The allegations of paragraph 11 contain legal conclusions to which no response is required. To the extent a response is required, Plaintiffs do not contest that venue is proper in this action. Plaintiffs deny the remaining allegations of paragraph 11.

BACKGROUND

A. FDA Approval of New Brand-Name Drugs

12. The allegations of paragraph 12 contain legal conclusions to which no response is required. Plaintiffs deny the remaining allegations of paragraph 12.

13. The allegations of paragraph 13 contain legal conclusions to which no response is required. Plaintiffs deny the remaining allegations of paragraph 13.

14. The allegations of paragraph 14 contain legal conclusions to which no response is required. Plaintiffs deny the remaining allegations of paragraph 14.

15. The allegations of paragraph 15 contain legal conclusions to which no response is required. Plaintiffs deny the remaining allegations of paragraph 15.

B. Generic Competition - Abbreviated New Drug Applications

16. The allegations of paragraph 16 contain legal conclusions to which no response is required. Plaintiffs deny the remaining allegations of paragraph 16.

17. The allegations of paragraph 17 contain legal conclusions to which no response is required. Plaintiffs deny the remaining allegations of paragraph 17.

18. The allegations of paragraph 18 contain legal conclusions to which no response is required. Plaintiffs deny the remaining allegations of paragraph 18.

19. The allegations of paragraph 19 contain legal conclusions to which no response is required. Plaintiffs deny the remaining allegations of paragraph 19.

20. The allegations of paragraph 20 contain legal conclusions to which no response is required. Plaintiffs deny the remaining allegations of paragraph 20.

21. The allegations of paragraph 21 contain legal conclusions to which no response is required. Plaintiffs deny the remaining allegations of paragraph 21.

C. NEXIUM 24HR® Esomeprazole Magnesium Delayed-Release Capsules, 20 mg and The Patent-in-Suit

22. Plaintiffs admit United States Patent No. 6,369,085 (“the ’085 patent”), entitled “Form of S-Omeprazole,” was duly and legally issued by the United States Patent and Trademark Office (“the USPTO”) on April 9, 2002 to AZ AB upon assignment from the inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Möller. Plaintiffs deny the remaining allegations of paragraph 22.

23. Plaintiffs admit United States Patent No. 7,411,070 (“the ’070 patent”), entitled “Form of S-Omeprazole,” was duly and legally issued by the USPTO on August 12, 2008 to AZ AB upon assignment from the inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Möller. Plaintiffs deny the remaining allegations of paragraph 23.

24. Plaintiffs admit the allegations of paragraph 24.

25. Plaintiffs admit the allegations of paragraph 25.

26. Plaintiffs admit the allegations of paragraph 26.

D. ANDA No. 207193 for Esomeprazole Delayed-Release Capsules, 20 mg

27. Plaintiffs admit the allegations of paragraph 27.

28. Plaintiffs admit the allegations of paragraph 28.

29. The allegations of paragraph 29 contain legal conclusions to which no response is required. Plaintiffs deny the remaining allegations of paragraph 29.

30. Plaintiffs admit that, in a letter dated December 22, 2014 (“the 2014 Notice Letter”), Perrigo notified Plaintiffs of the filing of its ANDA No. 207193 and that the ANDA included a Paragraph IV certification with respect to the ’085 and ’070 patents. Plaintiffs deny the remaining allegations of paragraph 30.

31. Plaintiffs deny the allegations of paragraph 31.

32. Plaintiffs deny the allegations of paragraph 32.

33. Plaintiffs admit the allegations of paragraph 33.

ANSWER TO FIRST COUNTERCLAIM

(Declaration of Non-Infringement of ’085 Patent)

34. Plaintiffs repeat and reassert all responses to paragraphs 1-33 as if they were incorporated herein.

35. Plaintiffs deny the allegations of paragraph 35.

36. Plaintiffs deny the allegations of paragraph 36.

37. Plaintiffs deny the allegations of paragraph 37.

ANSWER TO SECOND COUNTERCLAIM

(Declaration of Invalidity of ’085 Patent)

38. Plaintiffs repeat and reassert all responses to paragraphs 1-37 as if they were incorporated herein.

39. Plaintiffs deny the allegations of paragraph 39.

40. Plaintiffs deny the allegations of paragraph 40.

41. Plaintiffs deny the allegations of paragraph 41.

ANSWER TO THIRD COUNTERCLAIM

(Declaration of Non-Infringement of '070 Patent)

42. Plaintiffs repeat and reassert all responses to paragraphs 1-41 as if they were incorporated herein.

43. Plaintiffs deny the allegations of paragraph 43.

44. Plaintiffs deny the allegations of paragraph 44.

45. Plaintiffs deny the allegations of paragraph 45.

ANSWER TO FOURTH COUNTERCLAIM

(Declaration of Invalidity of '070 Patent)

46. Plaintiffs repeat and reassert all responses to paragraphs 1-45 as if they were incorporated herein.

47. Plaintiffs deny the allegations of paragraph 47.

48. Plaintiffs deny the allegations of paragraph 48.

49. Plaintiffs deny the allegations of paragraph 49.

AFFIRMATIVE DEFENSES

In response to Perrigo's counter claims, Plaintiffs assert the following affirmative and other defenses. In asserting these defenses, Plaintiffs do not assume the burden of proof with respect to any issue upon which applicable law places the burden of proof on Perrigo.

First Affirmative Defense

Perrigo's counterclaims, in whole or in part, fail to state a claim upon which relief can be granted.

Second Affirmative Defense

Counterclaims, in whole or in part, are non-justiciable.

Third Affirmative Defense

Plaintiffs have not knowingly or intentionally waived any applicable affirmative defense and reserve the right to assert and rely upon such other affirmative defenses as may become available or apparent during discovery proceedings. Plaintiffs further reserve the right to amend their Answer and / or their affirmative defenses accordingly, and / or to delete affirmative defenses that Plaintiffs determine during the course of subsequent discovery are not applicable.

RESPONSE TO PERRIGO'S PRAYER FOR RELIEF

Plaintiffs deny that Actavis is entitled to any relief as sought in its Counterclaims.

WHEREFORE, Plaintiffs therefore respectfully request the following relief:

- A. Dismissing Perrigo's Counterclaims with prejudice and denying all relief sought by Perrigo;
- B. Awarding Plaintiffs the relief requested in their Complaint; and
- C. Awarding Plaintiffs any further and other relief as this Court deems just and proper.

Dated: April 22, 2015

Respectfully submitted,

s/ John E. Flaherty
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Of Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2015, I caused the foregoing PLAINTIFF'S ANSWER TO PERRIGO COMPANY PLC, PERRIGO COMPANY, AND L. PERRIGO COMPANY'S COUNTERCLAIMS to be served on all counsel of record via the CM/ECF System and/or email.

By: s/ John E. Flaherty
John E. Flaherty